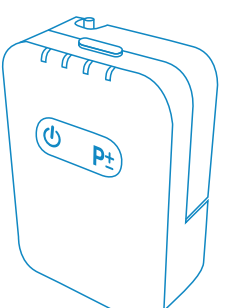
extriCARE®

Operating Manual

extriCARE® 1000

Negative Pressure Wound Therapy System



For Clinicians Use

ALLEVA MEDICAL

www.allevamedical.com

Rx Only

US Federal law restricts this device to sale by or on the order of a physician

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FOR CLINICIAN USE

1. Introduction

Alleva Medical's **extriCARE® Negative Pressure Wound Therapy (NPWT)** products consist of a family of negative pressure pumps and dressings intended to promote wound healing on patients in hospital or healthcare facilities settings. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts may benefit from using the **extriCARE® NPWT** system.

The **extriCARE® 1000 NPWT** Pump belongs to extriCARE's hybrid **Negative Pressure Wound Therapy (NPWT)** system, which also includes various sizes of **extriCARE® NPWT bandage dressings.** While the **extriCARE® 1000 NPWT** pump is intended to be used by a single user, it is not limited to single use of certain treatment duration. With a disposable 50cc canister, it allows for repeated collection of wound exudate, infections materials and tissue debris, as in a traditional NPWT system.

Weighing a bit more than 0.5lb, the **extriCARE 1000** operates on alkaline batteries. A target pressure of 80, 100, or 125mmHg can be delivered. User can also select between continuous and intermittent vacuum mode, in which the target pressure is held during the first 5 minutes of each cycle followed by 2 minutes at 20mmHg.

The **extriCARE® 1000 NPWT** Pump shall be used with the **extriCARE®** bandage dressing. The bandage dressing is an integrated dressing that does not require wound filling. Different sizes are available depending on wound geometry. For more information of each dressings, please consult with the Instructions for Use provided in each dressing pack or local distributor.

2. Indications for Use

The extriCARE® 1000 NPWT System is intended to generate negative pressure to remove wound exudates, infectious material, and tissue debris from the wound bed.

The extriCARE 1000 NPWT System is intended for use in wounds with low to moderate levels of exudate. Appropriate wound types include:

- Chronic wounds
- Acute wounds
- Traumatic wounds
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcer wounds (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

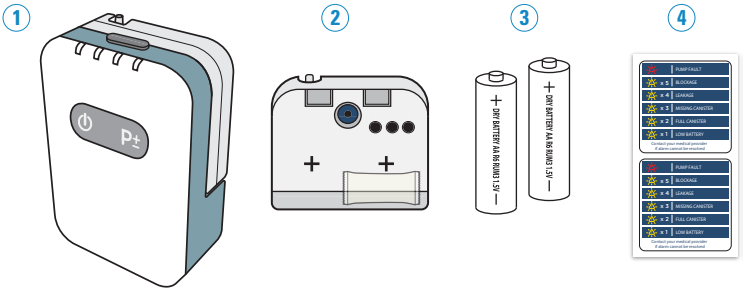
The extriCARE 1000 NPWT System is not intended for home use.

3. Contraindications for Use

extriCARE® 1000 should **NOT** be used in the following conditions:

- Exposed vessels, organs, or nerves.
- Anastomotic sites.
- Exposed arteries or veins in a wound.
- Fistulas, unexplored or non-enteric.
- Untreated osteomyelitis.
- Malignancy in the wound.
- Excess amount of necrotic tissue with eschar.
- Wounds which are too large or too deep to be accommodated by the dressing.
- Inability to be followed by a medical professional or to keep scheduled appointments.
- Allergy to urethane dressings and adhesives.
- Use of topical products which must be applied more frequently than the dressing change schedule allows.

4. Package Content



Each box contains:

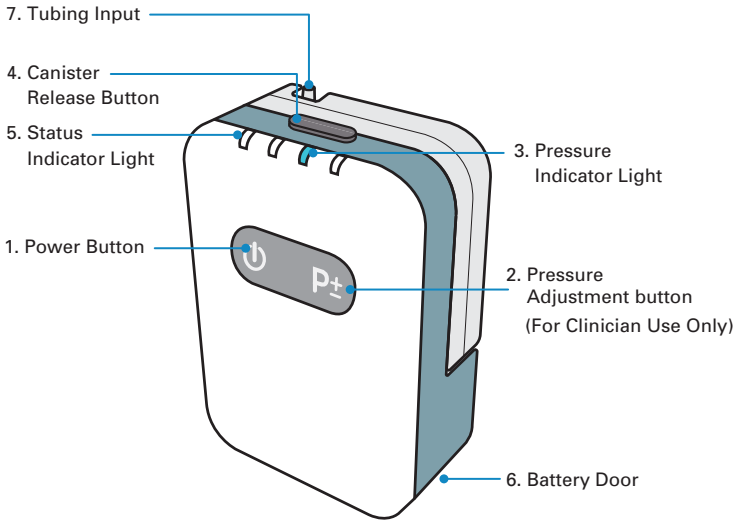
1. An **extriCARE® 1000 Negative Pressure Wound Therapy Pump** unit
2. An **extriCARE®** 50cc collection canister with solidifying agents
3. Two AA-size alkaline batteries
4. 2x Device Warning Sticker Labels

5. Accessories

The following accessories are available for purchase with the **extriCARE® 1000**. Please contact your local distributor for purchase orders.

1. Collection Canister: 50cc canister
2. Carrying Case: For use to carry the device
3. Wound Dressings: Please contact your local distributor for a complete listing of all currently available dressing options.

6. Features



1. **Power button:** press to start or stop a treatment
2. **Pressure Adjustment button:** press to adjust the target vacuum pressure from 80mmHg -> 100mmHg -> 125mmHg -> 80mmHg
3. **Pressure Indicator Light:** indicates the current vacuum pressure level
4. **Canister Release button:** press to release full canister
5. **Status Indicator Light:** dual color LED that indicate device status (See section 6 on page 9)
6. **Battery Door:** slide out to replace new batteries.
7. **Tubing Input:** Connection port used for the extriCARE® dressings to the collection canister.

7. Symbol List

	Keep Dry
SN	Serial Number
	Power Switch
ETL CLASSIFIED c ETL us Intertek 5011631	CONFORMS TO AAMI STD ES 60601-1, IEC STD 60601-1-6, AAMI STD HA 60601-1-11; CERTIFIED TO CSA STD C22.2 NO. 60601-1, CAS STD C22.2 NO. 60601-1-6, CSA STD C22.2 NO. 60601-1-11.
REF	Catalog / Model Number
	Consult Instructions For Use
IP22	Protection against solid objects of >12.5mm and modest vertical liquid ingress
	Operation temperature Limit (low left number denotes the lower temperature limit and upper right number denotes the upper temperature limit)
	Magnetic Resonance (MR) unsafe)
	Single Use Only
	Date of Manufacture
	Use-by Date
	Type BF applied part
 Rx Only	US Federal law restricts this device to sale by or on the order of a physician

8. Device Specifications

DIMENSIONS:	Height: 4.8" (12cm) Width: 3.2" (8cm) Depth: 1.3" (4cm)
WEIGHT:	0.46 lbs (0.21kg) / without batteries
VACUUM MODES:	Continuous and Intermittent
PRESSURE OPTIONS:	80 / 100 / 125mmHg
FREE FLOW RATE:	0.5LPM
BATTERY LIFE*:	36 hours
OPERATING CONDITIONS:	Temperature: +5°C to 40°C (41°F to 104°F) Humidity: 15-93%
BAROMETRIC PRESSURE:	80kPa-106kPa
STORAGE / TRANSPORTATION CONDITIONS	Temperature: -25°C to 50°C; Humidity: < 93% non-condensing
INGRESS PROTECTION:	IP22
PATIENT PROTECTION	Type BF
SHELF LIFE	3 Years

* tested on simulated wound models.

9. Operating Instructions

⚠ **Please consult Section 12 Warnings and Section 13 Precautions before reading this section.**

9.1 Dressing Application

extriCARE® 1000 Pump is compatible to be used only with extriCARE® bandage dressing incl. Follow detailed instructions that come with your extriCARE® Wound Dressing to apply the dressing.

The clinician may loosely place extra non-occlusive dressing material into areas of undermining and tunneling. The decision type of non-occlusive material used is based on clinician preference. Document the amount of additional packing material used.

extriCARE® wound dressings should be changed as needed.

- The initial extriCARE® wound dressings should be changed in 24 - 48 hours or when leaking, whichever comes first. extriCARE® wound dressings should not be left in place longer than 72 hours.
- If the extriCARE® wound dressings sticks to the wound, moisten with saline or water during removal. Adhesive remover may be used.
- Dispose of soiled extriCARE® wound dressings according to facility protocol.

Avoid outside sources wetting the extriCARE® wound dressings. The dressings should be protected from moisture during bathing or changed prior to reconnecting to the pump. Do not use the extriCARE® 1000 while showering or bathing. Always disconnect and remove pump from areas of moisture (bathing area or tub).

When using on a venous or other leg ulcer:

- Edema control must continue during wound treatment.
- Consider lower pressures when applied over fragile skin.

9.1 Operation Instructions (continued)

When applying the extriCARE® wound dressings over toes:

- A thin layer of petroleum jelly or other oil-based ointment may be applied to nails.
- Additionally, antifungal medication and a small amount of soft dressing material may be applied between each toe.

When used on the foot, aggressive measures should be taken to protect the foot and divert unnecessary pressure.

If the extriCARE® wound dressings is applied over a new graft or bioengineered tissue:

- It is recommended that a non-adherent open weave or fenestrated silicone contact layer be applied atop the wound between the graft and the NPWT dressing.
- Heavy petrolatum or similar products cannot be used as negative pressure will not have an impact on the wound surface.
- Additional care should be used during dressing change to prevent dislodging graft.

To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection controls with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status.

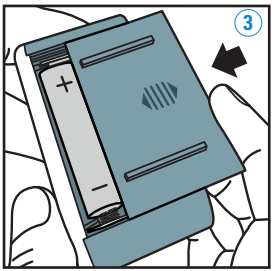
9.2 Inserting and Changing Batteries

Before changing batteries on extriCARE® 1000, first turn off the device and remove the collection canister (to avoid content from blocking the inlet port).

9.2 Inserting and Changing Batteries (continued)

Turn to the bottom of the device to locate the battery compartment door. Making use of the finger grooves, push the battery compartment door towards the back side of the device to expose the batteries. Place new batteries according to the position indicated on the label underneath.

To insert new batteries on extriCARE® 1000, turn to the bottom of the device to locate the battery compartment door. Making use of the finger grooves, push the battery compartment door towards the back side of the device to expose the batteries. Place new batteries according to the position indicated on the label underneath. To close the battery door, align the front edge of the battery door to the back of the battery compartment, then slide horizontally towards the front of the device. As shown in Figure 3.



9.3 Running a Treatment

To begin treatment, locate the Power button on the front of the device (See Section 6. Features).

Press down the Power button **for 3 seconds**. A chirp sound shall be heard and the treatment will automatically begin.

As the therapy begins, assess the dressing to ensure integrity of seal. The dressing shall start to have a wrinkle appearance as a result of vacuum pressure applied on it. Look for any audible air whistle sound coming from the dressing as it might indicates an air leak is present.

9.4 Adjusting Vacuum Pressure

When extriCARE® 1000 is used for the first time, the treatment will start at a default pressure of 80mmHg. To adjust the vacuum pressure, press the Pressure Adjustment button on the front of the device. User can adjust the pressure by pressing the button multiple times, until one of the three desired pressure levels (80/100/125mmHg) is selected. A chirp sound shall be heard with each press of the button, and the corresponding LED above each level will light.

The extriCARE® 1000 allows user to toggle between continuous and intermittent mode. The intermittent mode will deliver the target vacuum pressure for the first 5 minutes of each cycle, followed by a 2-minute 'resting phase' at 20mmHg. By factory default, the pump will start in continuous mode. To switch between the two modes, press the Pressure Adjustment button for 3 seconds. A chirp sound shall be heard when the switch is successful. The LED pattern above each pressure level shall also change – in continuous mode, the LED shall continuously be lit, whereas in the intermittent mode, the LED will be flashing.

extriCARE® 1000 remembers the last set pressure. When a treatment is resumed, it will automatically start at the pressure from last treatment.

9.5 Temporarily Disconnecting the Device

It might be necessarily to temporarily disconnect the device from the patient dressing during use (eg patient to take a shower). To temporarily disconnect the device from the dressing:

⚠ Please clamp off the tubing before disconnecting the luer connectors, to avoid exposing the wound to sudden pressure change and to the atmosphere.

1. Tightly clamp off the dressing tubing.
2. Twist off the tubing luer connector to unlock.
3. Turn the device off to stop the therapy.

Disconnecting the dressing from the device might require a dressing change or loss of vacuum pressure on the wound.

9.6 End of Treatment

To shut down the device, locate the Power Button on the front of the device and press down **for 3 seconds**. A chirp sound shall be heard, as all LED lights turn off.

To remove a canister, press the Canister Release button on the top of the device while pulling the canister away from the pump body. Release the button only when the canister is removed from the pump.

9.7 Disposal

The extriCARE® wound dressings, tubing, and canister can be disposed of according to policy for wound care dressings after use.

The extriCARE® 1000 pump is powered electromechanically by alkaline batteries that should be recycled according to the local regulations governing such products and to Waste Electrical and Electronic Equipment (WEEE) Directive.

9.8 Replacing Batteries.

Before replacing new batteries, turn off the pump and ensure any used canister is removed from the pump to avoid spillage.

10. Error Messages / Troubleshooting

Alarm Signal	Error Description	Action to Remove Alarm
3 beeps + RED LED flashing	Excessive vacuum pressure	Stop treatment and restart device. If problem persists, contact your local distributor.
2 beeps + RED LED flashing	Vacuum pump fault	Stop treatment and restart device. If problem persists, contact your local distributor.
1 beep + RED LED flashing	Air valve fault	Stop treatment and restart device. If problem persists, contact your local distributor.
5 beeps + YELLOW LED flashing	Severe blockage	Check tubing and canister for any signs of blockage; restart pump after addressing blockage issue.
4 beeps + YELLOW LED flashing	Severe leakage	Check dressing and tubing for any pleats or air bridge that might cause air leak.
3 beeps + YELLOW LED flashing	Missing canister or canister not detected	Ensure canister is properly installed. Remove and reinstall canister if necessary. Then restart treatment.
2 beeps + YELLOW LED flashing	Full canister	Replace the full canister with a new empty one. Then restart treatment.
1 beep + YELLOW LED flashing every 7 seconds	Low battery: only 10% of the battery capacity remaining	Replace with new batteries
1 beep + YELLOW LED flashing every 5 seconds	Critically low battery level: only 5% capacity remaining	Replace with new batteries

11. Maintenance and Replacement Parts

11.1 Maintenance and Replacement Parts

The extriCARE® 1000 NPWT Pump contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the extriCARE® device requires repairs, it should be returned to your durable medical equipment company (DME) or local distributor, or to Alleva Medical Devices directly.

No modification of the device is allowed.

Battery: If the device will not be in use for an extended period of time, the battery should be maintained removed from the unit, and stored in a safe and dry place.

11.2 Cleaning

The extriCARE 1000 and its carrying case can be wiped with a damp cloth using a mild household soap solution that does not contain bleach nor alcohol as they might degrade the front buttons. To keep the device clean, Alleva recommends weekly wiping down of unit, or when the unit becomes soiled during use. **DO NOT** immerse the device in water or else the electronics in the device will be permanently damaged. Water shall not be allowed to breach the device's outer casing and open port.

11.3 Disinfection

⚠ The extriCARE 1000 unit cannot be sterilized.

To avoid risk of contamination and contact with blood and body fluids, use personal protective equipment (PPE) such as medical procedure gloves. Prior to disinfection, remove the alkaline batteries from the unit. Wipe down all surface on the unit with a damp cloth and clean all visible soil or organic residues on the unit. Use a hospital grade disinfectant (such as Envirocide) and follow the direction indicated by the disinfectant.

DO NOT immerse the device in water or else the electronics in the device will be permanently damaged. Water shall not be allowed to breach the device's outer casing and open port.

12. Warnings

- Review this manual prior to using the extriCARE® 1000. If clarification is needed, contact technical personnel or extriCARE at 1-877-312-NPWT prior to use.
- Do not use the extriCARE® 1000 around explosive or flammable material.
- Do not use the pump in an MRI environment or hyperbaric chamber.
- Disconnect pump from dressing prior to MRI, hyperbaric chamber, or defibrillation according to dressing instructions found with each dressing kit.
- Negative Pressure Wound Therapy has not been cleared for use on children.
- Do not place this device at temperatures greater than 170°F for more than 2 hours which may cause a battery fire.
- If the alkaline batteries swell or leak, turn off the pump and use caution to remove the battery. Contact you provider to see if a replacement unit necessary.
- Avoid heat from a fireplace or radiant heater.
- Use the device in a clean environment - one that is free from dirt, dust, pets, hair etc.
- There is a risk of strangulation if one gets tangled in the tubing. Keep away from babies and children.
- The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if the extriCARE® 1000 unit is used near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment, metal detectors, or medical equipment such as diathermy and electrocautery. The extriCARE® 1000 unit shall be kept at least 30cm from such equipment, otherwise degradation of the performance of this equipment could result!
- CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move the pump out of the x-ray or scanner range. If the pump has been taken into the CT scan or x-ray range, check that the system is functioning correctly following the procedure.
- If using the extriCARE® 1000 pump, while inside the carrying case in an environment with temperature above 104°F (40°C), please avoid direct contact of the carrying case to the skin, since the temperature of the carrying case could rise to 109°F (43°C). Optionally, move to a cooler environment or remove the pump from the case.

13. Precautions

13.1 Be aware for any of the following conditions:

There are additional conditions to take into account before using Negative Pressure Wound Therapy, such as:

1. **BLEEDING:** There is a risk of bleeding/hemorrhaging with negative pressure wound therapy. If hemostasis cannot be achieved, if the patient is on anticoagulants or platelet aggregation factors, or if the patient has friable blood vessels or infected vascular anastomosis, he or she may have an increased risk of bleeding; accordingly, complete evaluations shall be conducted per the facility's guideline before beginning treatment and special care and monitoring of collected exudate level shall be exercised during treatment;
   If active bleeding develops suddenly or in large amounts during therapy, immediately disconnect the pump, leave the extriCARE® wound dressings in place, and take measures to stop bleeding. Seek medical attention immediately.

2. **VESSEL AND BONE PROTECTION:** Precautionary measures should be taken if any bones, vessels, ligaments or tendons are exposed. Additionally, sharp edges (due to bone fragments) require special attention; these areas should be covered and smoothed wherever possible. These conditions should be factored into the therapy prescription as the attending clinician sees fit.

3. **INFECTION:** Infected wounds and osteomyelitis pose significant risks for Negative Pressure Wound Therapy. If untreated osteomyelitis is present, therapy should not be initiated. Negative Pressure Wound Therapy should not be used to treat infections, and all infections should be treated and addressed prior to using the extriCARE® Negative Pressure Wound Therapy System.

4. **PATIENT SIZE AND WEIGHT:** Patient size and weight should be taken into account when prescribing therapy. In addition, small adults, young adults or elderly patients should be closely monitored.

13.2 Be aware for any of the following conditions (continued):

NOTE: If any of this information is not understood, contact the manufacturer before using the device.

6. **SPINAL CORD INJURY:** If a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate because of sympathetic nervous system stimulation), discontinue the therapy to minimize sensory stimulation and give immediate medical assistance.

7. **MODE:** In unstable anatomical structures, continuous rather than intermittent therapy is recommended to help minimize movement and instability. Continuous therapy is also recommended in patients with an increased bleeding risk, profusely exudating wounds, fresh grafts and/or flaps, and wounds with acute enteric fistulae.

8. **ENTERIC FISTULAS:** Wounds with enteric fistulas require special consideration to be effective in negative pressure wound therapy. If enteric fistula effluent management or containment is the only goal of such therapy, extriCARE® is not recommended.

9. **CIRCUMFERENTIAL DRESSING:** Do not use circumferential dressings.

10. **BRADYCARDIA:** Avoid placement of the extriCARE® Negative Pressure Wound Therapy Dressings next to the vagus nerve to minimize the risk of bradycardia.

11. **PERIWOUND SKIN:** Protect periwound skin with additional hydrocolloid, other transparent film, or other skin prep methods. Monitor skin for any signs of irritation or irregularity. If this occurs, stop treatment and consult physician.

13.3 Prior to Therapy

- Patient should be assessed, and measures should be taken to optimize and stabilize their medical condition. Nutrition, medication, blood glucose, blood pressure, and circulation as well as other medical issues should be addressed.

13. Precautions (continued)

- The wound should be recently debrided by whatever measure is appropriate and the amount of necrotic tissue should be minimized.
- Issues of infection should be addressed.

13.4 Periwound Skin

- Ensure that the skin that will be under the dressing is clean, dry, free of surfactants and oil. Any hair should be clipped.
- The periwound area should be cleaned and allowed to air dry. The use of a skin preparation wipe is also recommended.
- A thin film dressing or hydrocolloid may be used as additional protection.
- Monitor skin for signs of irritation or breakdown. Consider discontinuing treatment if this occurs and cannot be properly managed.

13.5 Dressing Management

In the extremely unlikely event that the extriCARE® wound dressings comes apart, all extriCARE® wound dressings materials must be removed from the wound prior to further treatment.

Clean and debride the wound as necessary. Any bleeding should be controlled. Follow facility protocol for wound prep and infection control. The type of extriCARE® wound dressings chosen for use is dependent on the wound type, size, and location. extriCARE® wound dressings size and type is labeled on each package.

- Care should be taken to avoid stretching of the dressing.
- Minimize pleating the extriCARE® wound dressings. Additional tape and urethane may be applied to secure the extriCARE® dressing in place and seals off air bridge formed from the pleats.
- Do not use as a circumferential dressing.

13. Precautions (continued)

- Additional wrap dressing may be applied over the extriCARE® wound dressings to further secure the extriCARE® wound dressings and provide additional support.
- If used on anatomically challenging areas or where adhesion is a problem, a thin layer of ostomy paste or wafer, hydrocolloid strips, or silicone strips may be applied.
- Refer to instructions for specific information regarding each extriCARE® wound dressings.
- In a non-infected and monitored wound, dressings should be changed no less frequently than every 72 hours. Disconnect the dressing from the drainage tubing and gently peel off to remove.

14. Warranty Information

LIMITED WARRANTY

Alleva Medical Products warrants its extriCARE® 1000 Negative Pressure Wound Therapy Pump ("Device") to be free from defects in workmanship and materials for a period of two (2) year from the date the Device is delivered to the original purchaser ("Warranty Period"). This Limited Warranty is extended only to the original purchaser and is non-transferable.

Alleva Medical Products' sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. This Limited Warranty excludes the battery, canister, canister clip, power plug, connection tubing, and dressings. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Alleva Medical Products' instructions, including, without limitation, the instructions contained in the Operation Manual.

THERE ARE NO OTHER WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.

TO THE EXTENT PERMITTED BY LAW, ALLEVA MEDICAL DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.

IN NO EVENT SHALL ALLEVA MEDICAL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, ALLEVA MEDICAL SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

15. Electromagnetic Compatibility Tables

Essential Performance. The essential performance of the extriCARE® 1000 Negative Pressure Wound Therapy unit is to maintain its pressure accuracy delivered to the wound site to an accuracy of ±10mmHg.

The extriCARE® 1000 is suitable for use in all establishments, including hospitals or clinical settings, as well as domestic establishments. The extriCARE® system should not be used in an magnetic resonance imaging (MRI) environment, in hyperbaric chamber environment (HBO), nor with defibrillation. Please disconnect device and/or remove dressings as instructed by your physician if these situations arise.

WARNING: Use of extriCARE® 1000 adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Alleva Medical may negatively affect EMC performance.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the extriCARE® 1000 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. See table below for additional details regarding recommended separation distances between portable and mobile RF communications equipment and the extriCARE® 1000.

15. Electromagnetic Compatibility Tables – RF Emissions Class B

Guidance and manufacturer's declaration – electromagnetic emissions		
The extriCARE® 1000 NPWT Pump is compliance for each EMISSIONS test specified by the standard, e.g. EMISSIONS class and group.		
Emissions	**Compliance**	**Electromagnetic environment-- guidance**
RF emissions CISPR 11	Group 1	The extriCARE® 1000 NPWT Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The extriCARE® 1000 NPWT Pump uses non-rechargeable AA alkaline batteries, and does not need to be connected to the public low-voltage power supply network. It is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity		
The extriCARE® 1000 NPWT Pump is compliance for each IMMUNITY test specified by the standard, e.g. IMMUNITY test level.		
Immunity test	**IEC 60601-1-2test level**	**Compliance level**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz	10V/m 80MHz-2.7GHz 80% AM at 1kHz

15. Electromagnetic Compatibility Tables – RF Emissions Class B (continued)

Immunity test	IEC 60601-1-2 test level	Compliance level
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not Applicable The extriCARE® 1000 is a battery powered device
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line; ±0.5 kV, ±1 kV and ±2 kV line-to-ground;	Not Applicable The extriCARE® 1000 is a battery powered device
Conducted disturbances induced by RF fields IEC 61000-4-6	3V 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	Not Applicable The extriCARE® 1000 is a battery powered device
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T: 0.5 cycle [a)] At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.	Not Applicable The extriCARE® 1000 is a battery powered device
	0% U_T: 1 cycle 70% U_T: 25/30 cycles [b)] Single phase: at 0°	
	0% U_T: 250/300 cycles [b)]	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

NOTE a) U_T is the a.c. mains voltage prior to application of the test level;
b) E.g. 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.

15. Electromagnetic Compatibility Tables – RF Emissions Class B (continued)

Proximity fields from RF wireless communications EQUIPMENT IEC 61000-4-3							
Test Frequency (MHz)	**Band (MHz)**	**Service [a)]**	**Modulation [b)]**	**Max. Power (W)**	**Distance (m)**	**Test Level (V/m)**	**Compliance level**
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430-470	GMRS 460 FRS 460	FM[c)] ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704-787	LTE-Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, Iden 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

NOTE
a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the extriCARE® 1000.

The **extriCARE® 1000** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **extriCARE® 1000** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **extriCARE® 1000** as recommended below, according to the maximum output power of the communications equipment.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **extriCARE® 1000**.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 0.58√P	80 MHz to 800 MHz d = 0.13√P	800 MHz to 2.7 GHz d = 0.25√P
0.01	0.058	0.013	0.025
0.1	0.18	0.041	0.079
1	0.58	0.13	0.25
10	1.8	0.41	0.79
100	5.8	1.3	2.5

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

16. Contact Infomation

Manufacturer

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